A randomized controlled trial comparing free-hand versus distal targeting jig-based for distal interlock screw placement

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NCT05613257
Carol Lin, MD, FAAOS
Charles Moon, MD, FAAOS

Cedars Sinai Medical Center

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PROTOCOL SUMMARY

Purpose and Knowledge to be Gained	• The purpose the research is to compare a modern proximally-based distal targeting device and free-hand techniques for placement of interlocking screws in lower extremity nailing
Research Procedures	• The primary research procedures are using jig-based distal targeter for lower extremity nailing orthopedic surgery procedures
Subject Population	• 18 years old and above • Undergoing intramedullary fixation of femur or tibia shaft for acute fracture or nonunion
Duration	• The study includes 1 visit. • The total study duration is 1 year

GENERAL INFORMATION

CSMC Co-Investigators	Milton Little, MD, FAAOS Geoffrey Marecek, MD, FAAOS Mark Vrahas, MD, FAAOS John Garlich, MD, MHDS Goran Stankovic, Study Coordinator
Sponsor/Funder	Stryker 2825 Airview Boulevard Kalamazoo, MI 49002 USA
Collaborating Institutions Involved in the Research	N/A

1.0 BACKGROUND, RATIONALE

Background: Interlocking screw placement in intramedullary nailing of femoral and tibial shaft fractures improves rotational and length stability. However, free-hand perfect circle techniques can be technically challenging and may take up to an hour with increased radiation exposure to the surgeon and patient (Whatling et al, Injury 2006). Newer technologies aimed at reducing fluoroscope use such as electromagnetically-based aiming devices may increase operative time (Maqungo et al, JOT 2014). Proximally-based jigs have been shown to reduce fluoroscopy time in cadavers (Miclau et al, Arch Orthop Tr Surg 1998), however have not been studied clinically.

We propose a prospective, randomized controlled trial comparing a modern proximally-based distal targeting device and free-hand techniques for placement of interlocking screws in lower extremity nailing.

2.0 STUDY OBJECTIVES

Outcomes:

- Primary outcomes: radiation exposure, time, accuracy of placement (right angle to rod).
    - Each distal interlock will be considered a separate outcome
        - The first fluoroscopy shot to localize the jig or obtain a perfect circle is considered start time. The surgeon will note the hour, minute, and seconds of the time based on the wall clock in the operating room.
        - The last shot to confirm complete seating of the screw will be considered end time. The surgeon will note the hour, minute, and seconds of the time based on the wall clock in the operating room.
- Secondary outcomes:
    - accuracy of placement (right angle to intramedullary nail).
    - Number of complete misses of the nail with the drill or the screw
    - comparison of learning curve between distal targeter and freehand techniques stratified by level of training
        - The level of training of the surgeon
        - Experience level of the surgeon
            - estimated number total number of intramedullary nails placed
            - time since the last intramedullary nail placement
            - estimated number of nails placed per month over the last year
            - number of times the surgeon has used the distal targeting system
    - Comparison of tibia vs femur antegrade nails

3.0 STUDY POPULATION

3.1 SELECTION OF THE STUDY POPULATION

Patients for this study will be drawn from the orthopedic trauma service. The majority of patients with these injuries will be approached in the inpatient setting, as they present through the emergency department. A small subset does present through clinic. All patients will be recruited to participate in the study after their femoral or tibia fracture repair.

3.2 INCLUSION CRITERIA

- 18 years old and above
- Undergoing intramedullary fixation of femur or tibia shaft for acute fracture or nonunion

3.3 EXCLUSION CRITERIA

- Prior ipsilateral tibial or femoral nail
- Patients who cannot have interlocking screws placed
- Pregnant patients
- For sub-study only: retrograde nails

3.4SUBJECT SCREENING AND ENROLLMENT

Data for this study will be collected prospectively, as the patients are admitted, and assessment of their injuries matches our inclusion and exclusion criteria. Radiographic imaging from medical records will be reviewed for the purposes of screening or contacting prospective subjects. The primary investigator and

Clinical Research Associate will access the records needed for screening from CS-Link, a HIPAA compliant electronic medical records system.

3.5 SUBJECT RECRUITMENT

Patients will be recruited from all full-time orthopaedic trauma faculty. The treating surgeon and/or clinical research associate will approach patients in person to recruit, enroll and consent them for the study. No advertisement will be used for this study.

4.0 STUDY DESIGN AND METHODS

This study will be a prospective, randomized control trial. Patients will be randomized to perform distal interlock screen insertion either by freehand or distal targeting for all lower extremity nails.

1. All patients undergoing femoral or tibial nailing will undergo one method of interlock placement starting on the first of the month starting with free-hand locking. The method of interlocking screw placement will then switch to jig-based screw placement at the first of the following month. The method of screw placement will alternate each week until enrollment is complete. This method of enrollment for clinical modalities that are already in common use has previously been described with the PREP-IT trials. [Slobogean et al, JAMA Netw Open 2020]
2. Due to the nature of the distal targeting jig's construction, there may be instances where its use is not possible due to interference with other surgical instrumentation, and an intraoperative decision must be made to place screws with the freehand technique. Patients randomized to the jig-based placement arm but are ultimately treated with freehand placement will be documented and reported as crossover patients (per the CONSORT framework).
3. Patients randomized to their respective groups will ultimately undergo intention-to-treat analysis.

5.0 DATA COLLECTION AND MANAGEMENT

5.1 DATA PROCUREMENT

Data for this study will be procured from patient x-ray images retrieved from the picture archiving and communication software (PACS). Deidentified x-ray measurements will be stored in a HIPAA compliant Cedars Box folder.

5.2 TIME PERIOD OF DATA UNDER REVIEW

Data collection will proceed prospectively from the date of study initiation and continue for approximately 1 year.

Information will be kept for a minimum of 2 years

5.3 VARIABLES COLLECTED

- The following data points/variables will be collected:
  - Patient name
  - MRN
  - Date of surgery
  - Length of surgery
  - Type of injury

- Type of procedure
- Radiation exposure

5.4 SOURCE DOCUMENTS

Source documents for this study will be radiographic images which we will take measurements from using PACS software and incorporated into a deidentified, secure database.

5.5 DATA COLLECTION AND STORAGE

- Data will be collected and stored electronically
- Stored data will be secured via REDCap
- Only the members of the research team will have access to data
- Patients will be deidentified at time of measurement

5.6 CONFIDENTIALITY AND SECURITY OF DATA

Secure storage: Data will be housed in a HIPAA-compliant secure storage system, like REDCap or Box, within the Cedars-Sinai network with access restricted to approved members of the research team.

Limited Access: Private identifiable information, will be accessible only to IRB approved study team members with current IRB training.

Unique ID Numbers: Each patient will be assigned a unique ID number.

Removal of Identifiers: Direct identifiers (like name or MRN) will be removed from the research records and destroyed as soon as scientifically possible and maintained only as long as necessary to abstract, analyze and verify data.

6.0 DATA AND SAFETY MONITORING

6.1 DATA AND SAFETY MONITORING PLAN

A data safety and monitoring plan will be used to ensure subject safety and data integrity. Any adverse event that may be harmful to a subject taking part in the study will be reported on the appropriate case report form. If the investigators are unsure about whether to report an occurrence as an adverse event, they are to contact the study's medical monitor. Adverse events will be assessed from the time of the start of the index surgery (first incision) and at all follow-up visits and will include a brief description of the event as well as the duration and the outcome. An event is considered a serious adverse event if it results in death or leads to serious deterioration of the health of the subject. Unanticipated adverse device effect will be defined as any serious adverse effect on health or safety caused by or associated with a device or software program. Both of these types of adverse events will be reported to the IRB within 24 hours.

6.2 QUALITY CONTROL AND QUALITY ASSURANCE

The clinical monitor will verify that appropriate data is recorded for all study subjects for whom informed consent is obtained; and that no study specific procedures or treatments are administered without informed consent.

7.0 STATISTICAL CONSIDERATIONS

7.1 STUDY OUTCOME MEASURES

- Primary Outcome analysis: 2 tailed T-test for average length of surgery (skin to skin), average time to place 2 interlocks (start time when nail is seated and surgeon states s/he is ready to proceed with distal interlocking screw placement). Average radiation used in microGrays. Femur vs tibia average time to place 2 interlocks and average radiation exposure.
    - To compare time and accuracy of placement only data from surgeons who have performed both DT and FH techniques more than 5 times will be included.
- Secondary outcomes: t-test accuracy of screw placement (perpendicular to nail)
    - Multivariate regression evaluating predictors of time to placement
        - Level of training
        - Number of cases performed
        - Number of interlocking screws placed
        - Time since last case
    - Learning curve assessment
        - Time of each interlocking screw placement will be correlated with number of interlocking screws placed
        - Time of procedure and accuracy of placement will be analyzed in increments of 5 cases to evaluate for number of cases required to reach plateau
            - Data will be stratified by level of training

7.2 SAMPLE SIZE CONSIDERATIONS

- Power: Based on a more recent paper from Konda et al, the average time for distal interlocking screw placement was 616 seconds in the control and 344 seconds in the distal targeting with an SD of 192 seconds. This suggests that a total of 30 patients would need to be enrolled for each cohort to detect a 44% decrease in the amount of time required for distal interlocking screw placement with the distal targeter with 90% power at 5% significance. (sealedenvelope.com power calculator on-line)
    - Estimating a 75% participation rate, we intend to enroll 60 patients (30 in each cohort – tibia and femur surgeries) that meet the sub-study criteria
    - Given that 9% of the currently enrolled patients (included in the main study) will not meet the sub-study criteria (retrograde nails instead of antegrade), we intend to enroll a total of 66 total patients for this study (includes patients for main study and sub study).

8.0 REFERENCES

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